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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/769,107	01/24/2001	Vincent P. Sandanayaka	WYTH0144-100/AM100182 01	4495
35139 7590 11/27/2007 Pepper Hamilton LLP/Wyeth 400 Berwyn Park 899 Cassatt Road Berwyn, PA 19312-1183			EXAMINER COVINGTON, RAYMOND K	
			ART UNIT	PAPER NUMBER
			1625	
			MAIL DATE	DELIVERY MODE
			11/27/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/769,107	<b>Applicant(s)</b> SANDANAYAKA ET AL.	
	<b>Examiner</b> Raymond Covington	<b>Art Unit</b> 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 September 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-14, 29-31, 33-39, 45-49 and 53 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 3-11 is/are allowed.
- 6) ☒ Claim(s) 1, 2, 12-14, 29-31, 33-39, 45-49 and 53 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 45 and 47 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling compounds of formula IX where R<sub>4</sub> may contain a piperidine, pyrroly, pyridine, thiophene or dioxo substituent it does not reasonably provide enablement for the broader scope in claims dependent thereon. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. Specification provides no guidance as to what other rings, for example, might be suitable and there is no basis in the prior art directed to similar compounds having the same activity as herein.

The Wands factors are again applied as set forth in the previous office action. Applicants' comments have been noted and considered but are not deemed persuasive of patentability.

There is no reasonable basis for assuming that the myriad of compounds embraced by the claims will all share the same physiological properties since they

are so structurally dissimilar as to be chemically non-equivalent and further would not be produced by the same process. Note In re Surrey 151 USPQ 724 regarding sufficiency of disclosure for a Markush group.

There is insufficient disclosure of starting materials that would place such a diverse genus of compounds in possession of the public in the event of a patent grant. The limited number of examples do not enable the preparation of such a diverse group the compounds embraced by the claims as presently recited, e.g. triazo containing heterocyclic rings.

There is insufficient disclosure of starting materials that would place such a diverse genus of compounds in possession of the public with a reasonable assurance that such an alleged genus of compounds could be made by the same process. See In re Fouche 169 USPQ 429 ((CCPA 1971)). This is particularly true where large groups such as heteroaryl may sterically hinder or may prevent the making of the starting materials, intermediates or final products.

The numerous substituent variables and their voluminous complex meanings and their seemingly endless permutations and combinations make it virtually impossible to determine the full scope and complete meaning of the claimed subject matter. As presented, the subject matter cannot be regarded as being a clear and concise description for which protection is sought.

Claim 46 is rejected to the extent it reads on and depends from a rejected base claim.

Claims 48 and 49 are again rejected under 35 U.S.C. 112, first paragraph, because the specification, does not reasonably provide enablement for treating any disease or condition. The specification does not enable any physician skilled in the art of medicine, to make the invention commensurate in scope with these claims. regarding applicants' comments see section D below. It is noted that inhibition response to a specific enzyme with a specific compound does not equal treatment of any or all of multiple classes of conditions. Applicants' comments have been noted and considered but are not deemed persuasive of patentability.

The Wands factors are applied as in the previous office action. Applicants' comments have been noted and considered but are not deemed persuasive of patentability.

It is agreed that TNF- $\alpha$  may be involved in many diseases. However, as applicants indicate, the precise role is not known for many diseases as applicants stated on page 3 20 of the response is only a potential one.

Further, experimentation is required to determine the precise role of TNF- $\alpha$  and thus whether inhibition of its processing would predictably be beneficial.

Not only is the significance of TNF- $\alpha$  in these diseases unclear, the effect of inhibition of processing is unknown.

There is no guidance as to whether TNF- $\alpha$  levels would be affected in any disease in which TNF- $\alpha$  is released.

Furthermore, applicants has merely provided evidence that a single compound can inhibit TACE (p. 75). Other in vitro experiments are outlined but performed, and there is no nexus provided between the inhibition of gelatinase or collagenase and the treatment of any disease. Thus it would require undue experimentation for the artisan to use the compounds as claimed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 48 is again rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 48 is unclear. Defining a disease by its (their) underlying cause renders the scope of intended uses indeterminate since the claim language may read on diseases not yet known to be caused by or affected by such action or in ways not yet understood.

Claims 1, 2, 12-14, 29-31, 33-39 and 53 are again rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The claims do not positively recite the method steps of the claimed process. There is not recitation of how formula V is converted to formula I, the final product.

Claims 3-11 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond Covington whose telephone number is (571) 272-0681. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres at telephone number (571) 272-0867.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair->

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direct.uspto.gov. Should you have questions on access to the Private PAIR system,  
contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Janet Andres  
SPE  
Art Unit 1625

*RKC*

RKC

  
JANET L. ANDRES  
SUPERVISORY PATENT EXAMINER